



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 9 2012

Food and Drug Administration  
Rockville MD 20857

Re: ONSIOR  
Patent Nos. 6,291,523; 7,115,662  
Docket Nos. FDA-2011-E-0677  
FDA-2011-E-0678

The Honorable David J. Kappos  
Under Secretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Kappos:

This is concerning the applications for patent term extension for U.S. Patent Nos. 6,291,523 and 7,115,662 filed by Novartis Animal Health US, Inc., under 35 U.S.C. 156. The animal drug product claimed by the patents is ONSIOR (robenacoxib), which was assigned new animal drug application (NADA) No. 141-320.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. 156(f)(1).

The NADA was approved on March 8, 2011, which makes the submission of the patent term extension applications on April 27, 2011, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, reading "Jane A. Axelrad", is positioned above the typed name.

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

Kappos - ONSIOR  
Patent Nos. 6,291,523 and 7,115,662  
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cc: Leslie Fischer  
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